

AUG 27 2003

Peter J. Petersan, Esq.
The Humane Society of the United States
2100 L Street, NW
Washington, DC 20037

Dear Mr. Petersan:

The Food Safety and Inspection Service (FSIS) has completed its review of the November 28, 2007, petition submitted by you on behalf of The Humane Society of the United States and various other organizations requesting that the Agency prohibit for use as human food foie gras made from the livers of force-fed poultry. The petition asserts that foie gras is an adulterated and diseased product that is "unsound, unhealthful, unwholesome, or otherwise unfit for human food" under the Poultry Products Inspection Act (PPIA) (21 U.S.C. 453(g)(3)). As discussed below, FSIS has determined that the presence of fatty change in a duck or goose liver used to produce foie gras alone does not render the foie gras adulterated or otherwise unfit for human food. The Agency has also concluded that additional research is needed on the potential human health effects associated with the consumption of foie gras. Therefore, we are denying your petition. We apologize for the delay in responding to your petition, but our resources for petition review are limited.

According to the petition, force-fed foie gras is a diseased poultry product made from fatty, degenerated duck or goose liver. More specifically, the petition asserts that the animal raising practices associated with the production of foie gras cause ducks and geese to contract "hepatic lipidosis," a fatty liver condition that renders the liver "unfit for human food" within the meaning of the adulteration provisions of the PPIA.

When evaluating the petition, FSIS considered the condition of the livers of ducks and geese used to produce foie gras, and the Agency acknowledges that the appearance of the livers of these birds would be characterized as affected by hepatic lipidosis. However, the Agency also determined that the fatty liver used for foie gras is the result of a physiologic condition, i.e., overwhelming of the hepatocyte's ability to process and export fat, rather than disease. Thus, while the appearance of the foie gras liver, both grossly and microscopically, might be considered abnormal because it differs from a liver from a bird on a diet that contains less fat and carbohydrate, the fatty changes are exactly those that would be expected due to the altered physiologic state of the bird. Thus, the condition of the foie gras liver is not a "disease," as suggested in the petition, because it is normal for the bird in that state. While there are conditions in which hepatic lipidosis, in conjunction with other changes, such as hemorrhage, necrosis, inflammation, or fibrosis, would be considered part of the disease process, FSIS does not consider hepatic lipidosis due to a physiologic condition, to be one of them.

To support the action requested in the petition, you also submitted an article published in the Proceedings of the National Academy of Sciences that, according to the petition,

suggests that that consumption of foie gras may trigger the onset of Secondary Amyloidosis in certain people, including those with inflammatory diseases, such as rheumatoid arthritis.¹ In the study, researchers analyzed several commercial sources of foie gras and found that they contained amyloid. Mice genetically susceptible to develop Secondary Amyloidosis were then injected with or fed amyloid extracted from the foie gras. Afterwards, the study reported that a majority of these animals developed amyloid deposits in the liver, spleen, intestine and other organs.

FSIS has reviewed the article and has determined that it relays little information that has not previously been reported in other studies on amyloidosis in waterfowl. Amyloidosis is fairly common in ducks in general, not just those used to produce foie gras. It is not uncommon to find both amyloidosis and hepatic lipidosis in the same bird. Because of this, it is not surprising to find that the foie gras in the study contained amyloid enhancing factor.

In addition, the findings in the study are based on the administration of amyloid to genetically susceptible mice under experimental conditions. The study does not present any data to establish a link between the presence if amyloid in foie gras and the development of human disease. To establish any link between the two conditions, or the potential effect on human health of consuming amyloid, will require additional scientific study.

For the reasons stated above, FSIS has determined that foie gras made from the livers of force-fed poultry is not an adulterated and diseased product and is not "unsound, unhealthful, unwholesome, or otherwise unfit for human food" under the Poultry Products Inspection Act (21 U.S.C. 453(g)(3)). Therefore, FSIS is denying your petition.

You may contact Mary Porretta, Petition Manager, Policy Issuances Division, at (202) 720-5627, if you have any questions regarding the status of your petition.

Sincerely,

A handwritten signature in black ink, appearing to be 'S' inside a vertical rectangle, representing Philip S. Derfler.

Philip S. Derfler
Assistant Administrator
Office of Policy and Program Development

¹ Alan Solomon, MD, *et al.*, *Amyloidogenic Potential of Foie Gras*, 104 PROC. NAT'L ACAD. SCI. 10998 (2007)